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## A Double-Blind, Controlled Ph 2b Study of the Safety and Efficacy of Modified Stem Cells in Patients with Chronic Motor Deficit from Ischemic Stroke

### Grant Award Details

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A Double-Blind, Controlled Ph 2b Study of the Safety and Efficacy of Modified Stem Cells in Patients with Chronic Motor Deficit from Ischemic Stroke

**Grant Type:** Clinical Trial Stage Projects

**Grant Number:** CLIN2-10344

**Project Objective:** A Double-Blind, Controlled Ph 2b Study of the Safety and Efficacy of Modified Stem Cells in Patients with Chronic Motor Deficit from Ischemic Stroke.

**Investigator:**

**Name:** Damien Bates

**Institution:** SanBio, Inc.

**Type:** PI

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**Disease Focus:** Stroke, Neurological Disorders

**Human Stem Cell Use:** Adult Stem Cell

**Award Value:** \$19,998,580

**Status:** Active

### Grant Application Details

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**Application Title:** A Double-Blind, Controlled Ph 2b Study of the Safety and Efficacy of Modified Stem Cells in Patients with Chronic Motor Deficit from Ischemic Stroke

**Public Abstract:****Therapeutic Candidate or Device**

Modified adult donor bone marrow-derived mesenchymal stem cells (Modified MSC)

**Indication**

Chronic motor deficit secondary to ischemic stroke

**Therapeutic Mechanism**

Local intracerebral delivery of Modified MSC adjacent to motor pathways stimulate via a paracrine mechanism neurogenesis & angiogenesis by the release of FGF-2, other trophic factors & ECM proteins. The net effect is alteration of synaptic transmission appearing to improve motor function in a hitherto inhibitory milieu. Collectively, these properties are thought to promote neuroplasticity seen as the basis for improvement in motor function observed in stroke patients treated with Modified MSC.

**Unmet Medical Need**

There are no proven medical treatments available for chronic disability secondary to stroke. Results from our Phase 1/2a study suggest that Modified MSC has a favorable safety profile and the potential to improve motor function in these patients.

**Project Objective**

Complete Ph 2b trial; EOP2 meeting; Enable Phase 3

**Major Proposed Activities**

- Completion of Phase 2b ACTISIMA clinical trial.
- Manufacture Modified MSC clinical supplies.
- Further investigate and validate the mechanisms of action to identify additional measures of potency and validation of associated bioassays.

**Statement of Benefit to California:**

In 2012, 96,500 Californians suffered strokes with approximately 67,500 patients experiencing residual disabilities. Results from our Phase 1/2a study suggest that Modified MSC has a favorable safety profile and the potential to improve motor function in these Californians. This research will involve many clinical & research sites throughout California which will have a positive effect on the state's economy and scientific profile.

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**Source URL:** <https://www.cirm.ca.gov/our-progress/awards/double-blind-controlled-ph-2b-study-safety-and-efficacy-modified-stem-cells>